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Description

The present invention relates to a device suitable for the administration of a therapeutic substance, for example insulin, especially but not necessarily on an intermittent basis.

Insulin-dependent diabetics rely upon subcutaneous doses of insulin administered, and usually self-administered, by means of a syringe and a hypodermic needle. This involves the psychological trauma of self-injection, as well as the inconvenience of the overall procedure. Insulin may also be delivered by electrical, mechanical or hand-operated pumps.

Alternatively, it is also possible to use an indwelling needle through which insulin may be administered. The facility to give injections via indwelling needles is not new (see, for example U.S. Patent Specification No. 4,568,335), but there are two problems with such indwelling needles as currently available. First, the needles are sharp and made of rigid steel, which can be painful in situ; and secondly, in the injection port attached to the needle there is a large "dead-space", that is the space in the device within which insulin will be withheld instead of being expressed to the patient, which gives rise to problems - not merely the problems involved in taking account of the dead-space when calculating doses of insulin, but also the further problems which arise when injecting more than one species of insulin. Furthermore, the kind of needles employed for this purpose and their associated apparatus are often designed for giving large volumes of solution, or for sampling blood. Still further, as shown for example in the above-mentioned United States Patent Specification the connection between the feed syringe or the like and the needle cannot be broken, since there is no seal in or associated with the needle itself.

In an effort to eliminate dead-space problems, there has been marketed in the U.K. a so-called "button" infuser, which is said to have a nominal "dead-space" volume of less than 0.33 units of U-100 insulin. However, that "button" infuser again has a steel needle, leading to discomfort; and, while this device is self-sealing, it is difficult to ensure that the intermittent injection needle (which has to be inserted into the indwelling needle) is always during its insertion accurately placed, so that first it does not over-penetrate and engage the plastics material in the hub of the indwelling needle, and so that secondly it does not under-penetrate and fail to enter the indwelling needle lumen beyond the self-sealing diaphragm. The cause of this difficulty is that in this known "button" infuser the self-sealing diaphragm takes the form of a relatively thick seal at the mouth of the device; or in other words, the seal is positioned so that it must be pierced before the device can be entered, and this in practice causes entry problems. Thus, for example, where the device is worn say on the patient's abdomen, the patient must look down and, with a fairly restricted view of the mouth of the device, attempt to penetrate a relatively thick seal, without either under-penetrating or over-penetrating as described above.

DE-A-3147609 discloses a device for indwelling in a patient and through which a catheter may be inserted. The device includes a separator having a channel which when closed can prevent egress of blood. At the same time, because the channel dimensions are smaller than those of the catheter it grips the catheter when **in situ** to prevent motile retraction thereof.

US-A-4121585 discloses an injection device for use in an IV administration set. The device includes a Y-connector wherein the injection part includes two spaced-apart piercable diaphragms. One or more syringes may be berthed between the diaphragms, advanced at will through the second diaphragm and then retracted to lie between them.

We have now found surprisingly that the disadvantages of the known "button" infuser can be avoided, while at the same time still having a dead-space of only relatively small volume, by disposing the seal in the body of a cannula hub, the seal being disposed not only adjacent the hub-end connected to the cannula, but also at the distal end of a needle guide-passage through the hub, which ensures correct alignment of the injection needle as it passes through the hub and penetrates the seal.

Accordingly, the present invention provides a device suitable for use in the intermittent or even continuous administration of a therapeutic substance (such as insulin), which device comprises a cannula of biocompatible plastics material for indwelling in a patient and defining a through-passage, together with a hub also defining a through-passage, a seal being disposed therebetween the respective cannula and hub passages, the arrangement of the respective passages themselves and together with said seal being such as to permit a needle to penetrate the hub and cannula through them and, when of sufficient length, to extend beyond the distal end of the cannula, the through-passage of the hub also being so constructed and arranged as to guide an injection needle passed therethrough so that the needle thus guided will pass through the seal at a position where the needle is aligned with the through-passage of the cannula, which device is characterised in that said seal comprises a self-sealing diaphragm isolating the respective cannula and hub passages, which self-sealing diaphragm is one of a natural rubber, a silicone rubber or another self-sealing elastomeric

polymer.

In use the device of the invention can be positioned with its cannula implanted subcutaneously in the patient by means of a skin-puncture needle which may be already disposed in the device or inserted therein when required, and which extends beyond the distal end of the cannula. Once the cannula of the device has thus been implanted, the skin-puncture needle is withdrawn, and the device can be taped in place to be left in situ for use in the administration of one or more doses of insulin or the like as necessary. For example, but fairly typically, the device may be left in situ for four days, and over that period of time up to 16 doses or more of insulin may be injected through the device, effectively involving only the single initial skin puncture.

For the purpose of giving an injection of insulin or the like the needle of a hypodermic syringe containing the insulin or the like is passed along the through-passage in the hub. Once it reaches the end of that passage, the needle passes through the separator means. Preferably, its movement past a position where its tip is just beyond the separator means is then prevented by including in the device of the invention overpenetration-restraining means. Conveniently, this can be accomplished by arranging the hub so that the overall penetrable length of the through-passage therein is just a little shorter than a standard hypodermic needle. For example, one typical standard hypodermic needle for insulin injection is an 11 mm needle.

By providing a hub having a through-passage and which includes a self-sealing diaphragm or like separator means at the distal end of the passage adjacent the entrance to the cannula, accurate placement of the injection needle can be accomplished. Thus, in the first place accurate alignment between the needle and the cannula lumen can be accomplished by the arrangement of the through-passage in the hub; and secondly, the length of the hub can be chosen so that the desired amount of penetration of the diaphragm or the like is achieved, but no more.

In the device of the invention, the nominal "dead-space" volume generally may be any chosen volume of about 0.75 units of U-100 insulin or below. Thus, while in theory larger "dead-space" volumes may be chosen - since notionally at least the self-sealing diaphragm or the like always holds a small volume of insulin in the cannula passage beyond the diaphragm seal - nevertheless because "dead-space" volumes of about 0.75 units of U-100 insulin or below are easily achieved with the device of the invention, as described herein, and because the smaller the "dead-space" volume the more flexible the device can be in terms of the ability to avoid the need to flush when changing insulin dosage or species, "dead-space" volumes below the figure stated above are generally preferred. More preferably, however, the "dead-space" volume should be in the range of from about 0.5 to about 0.3 units of U-100 insulin.

Furthermore, in the device of the invention the mouth of the through-passage in the hub most remote from the cannula is desirably so shaped that the passage has a conical or funnelled entrance zone. By providing a conical or funnelled entrance zone, penetration of the mouth of the through-passage in the hub by the hypodermic needle is facilitated even when the cannula is positioned in situ, and even though the patient's view of the mouth of the through-passage may be restricted. Also, the conical or funnelled entrance zone provides a guide portion permitting easy penetration of the mouth of the through-passage even where the passage mouth is covered, as is preferred, by a self-sealing cap or the like, as described below. It will be appreciated that ingress of dirt or other undesirable material into the device can be avoided if the hub includes means such as a cap to prevent such ingress.

As indicated above, the device of the invention generally may remain in situ for a period in the region of about 4 days, with a typical period being say from about 2 to about 5 days. Since the device includes a cannula of biocompatible plastics material, irritation generally is kept to a minimum, and the plastics cannula is thus less noticeable to the wearer once placed in situ than a corresponding steel cannula. Moreover, the patient can feel confident once the device is in situ that the next-following series of injections (say 16 or more further injections) can be accomplished without trauma and, furthermore, that no insulin loss will occur. That is because the injection needle is securely guided to proper placement in the injection port, and generally cannot be misdirected or misplaced.

Preferably, the cannula comprises a flexible synthetic plastics material, generally formed of one or more synthetic polymers, for example, of one or more fluorocarbons such as "Teflon". It is of course especially preferred that the cannula should comprise a medical-implant grade synthetic polymer. In addition, it is also preferred that the hub should comprise a biocompatible material suitable for use with drugs and next to skin. Examples of such materials are polypropylene and polyurethane materials.

Furthermore, in the device of the invention the hub is preferably a two-part hub-assembly, preferably with the separator means located between the two parts of the hub. More preferably, in such a construction a first hub-component comprises a body defining an axial bore which at its distal end is adapted to receive the proximal end of the

cannula, whereby the through-passage of the cannula is positioned in communication with the bore, and at its other end a socket communicating with the bore and adapted to receive (mate with) a plug-portion of a second hub-component, also comprising a body defining an axial bore, the bores in the respective first and second hub-components being aligned to communicate with each other and together defining the through-passage in the hub assembly. By providing such a two-part construction, a self-sealing diaphragm can then be sandwiched between the two hub-components e.g. between the distal end of the plug-portion and the base of the socket.

Preferably, the first hub-component includes an elongated nose portion at its distal end, within which a significant portion of the proximal end of the cannula can be accommodated, thereby providing support for the cannula and a means of securing the cannula to the hub, for example, by adhering the outside of the cannula to the inside of the nose. Additionally or alternatively, the bore in the first hub-component may be of greater diameter than the diameter of the through-passage, where it accommodates the tip of the proximal end of the cannula, thus providing an annular abutment for the tip of the proximal end of the cannula, to permit securing of the cannula to the hub.

In order to minimise pain during the initial injection through the patient's skin, the cannula can advantageously be shaped at its distal tip so that it tapers towards and close to the projecting tip of a skin-puncture needle (when the latter is disposed within the device, to enable it to penetrate the skin), and so that its front edges are relatively smooth.

Also, while we have indicated above that the device may be taped in place, other fixing means may be employed. Thus, for example, the hub of the device may include a self-adhesive support portion to enable the hub to adhere to the patient's skin when pressed thereagainst.

The device of this invention has been described above mainly in relation to its use with insulin, but it is to be understood that its utility is not necessarily confined to the administration of insulin but extends to the administration of any therapeutic substance which requires the patient to be injected (or above all to inject himself) frequently - say a number of times in each day. Thus, for instance, the device can prove valuable in the regular administration of morphine.

Furthermore, while the device has been primarily designed and therefore is particularly suitable for self-administration on an intermittent basis, it should be appreciated that it may also be used in conjunction with apparatus for continuous administration. Thus, besides being useful in the case where injections are given through the cannula as and when required (either by means of a standard syringe or a cartridge device) the hub may be adapted to be connected to means continuously to supply a therapeutic substance such as insulin or morphine. Such means are currently available and comprise a reservoir, a pump, a supply line and a needle for injection purposes. Also, various kinds of sophisticated electronic means may be included to achieve any necessary or desired control over the doses pumped from the reservoir to the needle via the supply line.

For such use, the device preferably will include a hub having means to provide or accommodate a supply line lock fitment. Thus, for example, the hub may be formed with say one or more Luer lock lugs, or with means to accommodate say a Luer lock adaptor.

Alternatively and preferably, the hub is of a two-part hub-assembly as described previously, and the hub-components are arranged so that the plug-portion of the second hub-component includes an annular flange, and the plug-portion mates with the socket in the first hub-component in such a manner that an annular locking groove is formed between the flange and the end of the first hub-component adjacent the flange.

Such an annular groove may be used to accommodate the front arms of a clip, for example, a hinged clip like that described in co-pending British Patent Application No. 85-17976 (Publication No. 2,161,709A) and European Patent Application No. 85-30-5093.8 (Publication No. EP 0169704A). A said clip may be defined as one having a body portion including at or adjacent one end means, such as a pair of opposed depending arms, engageable with the supply line or supply line connector, and at or adjacent its other end a pair of opposed depending arms engageable with the groove, the said means being arranged to permit the said arms engageable with the groove to move into and out of engagement.

Preferably such a clip may be one for use with a supply line which includes a pair of trunnion pins upstanding on either side of an end portion of the line. The clip then may be formed with a first pair of opposed arms each including an aperture so that they can be sprung over the trunnion pins and the clip thereby pivotably mounted on the end portion of the line.

The invention also includes a device as defined and described herein in combination with a skin puncture needle. Such a combination may be put up for use packaged together with the needle disposed in the device in a sterile pack. The pack preferably will include a self-sealing cap as described herein to prevent ingress of dirt in use.

In addition, the invention includes a device as

defined and described herein in combination with a supply line arrangement. Preferably, in such a combination the supply line arrangement includes mounted on an end portion of the line a needle adapted to penetrate the separator means of the device and a pivotal clip engageable with the hub of the device to lock together the device and the supply line. More preferably, the hub may be a two-part hub-assembly as described above with an annular locking groove and the clip may be as defined above. Also, the supply line arrangement may include a reservoir and/or a pump and/or electronic control means as described above.

In order that the invention may be well understood a preferred embodiment thereof will now be described in more detail, though only by way of illustration, with reference to the accompanying drawings, in which:-

Figure 1 is a mainly cross-sectional view, taken in a plane through the axis, of an embodiment of the device of the invention;

Figure 2 is an essentially similar, mainly cross-sectional view, of the embodiment of Figure 1, again taken in a plane through the axis of the device, showing a cap-like closure member mounted thereon to prevent ingress of dirt, and a skin-penetration needle fitted therethrough in its operative, skin-penetrating position;

Figure 3 is a non-sectional external view of the embodiment of Figure 2, taken in slight perspective from the distal end of the skin-penetration needle;

Figure 4 is a mainly cross-sectional view of the same embodiment of the device, generally similar to Figure 2 but on an enlarged scale, and in which the skin-penetration needle has been removed and replaced by the hypodermic injection needle of a syringe;

Figure 5 is a diagrammatic side view of a combination of a device in accordance with the invention shown in unlocked association with a supply line arrangement;

Figure 5(a) shows the clip of Figure 5 separate from the supply line arrangement; and

Figure 6 shows the combination of Figure 5 locked together.

Referring to Figures 1 to 4 of the drawings, the device shown comprises a cannula 1 having a delivery (through) passage or lumen 16. The cannula is formed of biocompatible flexible synthetic plastics material and, therefore, is capable of indwelling in a patient for a period of several days after subcutaneous insertion thereof. The proximal end of the cannula 1 is mounted and secured (e.g. by adhesive) at the distal end of a two-part hub assembly, generally indicated by the numeral 2, also formed of a biocompatible but relatively rigid plastics material, and having a through-passage 3 passing axially therethrough which communicates with the delivery passage or lumen 16 within the cannula 1. The hub-assembly 2 comprises a first hub-component 4 and a second hub-component 5, each having an axially-disposed bore therein which, in the assembled position (as shown), is aligned with the axially-disposed bore in the other hub-component, and which together constitute the through-passage 3. The hub assembly 2 is formed by mating a cylindrical socket 6 in the proximal end of the first hub-component 4 with a plug-portion 7 on the distal end of the second hub-component 5. An annular collar 17 around hub-component 5 prevents the plug-portion 7 from mating fully with the socket 6 in the first hub-component 4 and, within the cylindrical chamber between the base of the socket 6 and the end of the plug-portion 7, there is accommodated a self-sealing diaphragm 8, formed of silicone rubber or another elastomeric polymer. The diaphragm 8 is thus sandwiched between the hub-components 4 and 5, blocking communication between the axial bores therein and thus normally sealing the through-passage 3. However, the diaphragm 8 may easily be penetrated by a needle which is passed down the through-passage 3 to penetrate through the diaphragm.

In order to implant the indwelling cannula 1 subcutaneously in a patient, in the manner which will be described in more detail hereinafter, a skin-penetration needle 14 (see Figures 2 and 3) is passed through the device down through-passage 3 until its tip protrudes beyond the distal end of cannula 1. It will be seen that, in order to ease the implantation of the cannula 1 subcutaneously into the patient, its distal end 1' is externally tapered and fitted as closely as possible about the protruding end of the sin-penetration needle 14.

The proximal end of the second hub-component 5 is provided with an open-mouthed, conical indent generally designated by the numeral 9, whose conical walls 9' are co-axial with and whose apex communicates with the through-passage 3. As can best be appreciated from Figures 2 and 4 a skin-penetration needle (Figure 2) or a hypodermic injection needle (Figure 4) entering the device, is funnelled into alignment with the through-passage 3 by this open-mouthed conical indent 9.

As appears from Figures 2 and 4, in order to prevent ingress of dirt or other undesirable material into the open mouth of the conical indent 9 defined by walls 9', a tubular-skirted cap generally indicated by the numeral 10, and formed of elastomeric material, is removably fitted across the otherwise open mouth of the conical indent 9. There it is held in position by its depending tubular walls 11 adapted to embrace part of the cylindrical outer surface of the main body portion of the

second hub-component 5.

As best appears from Figure 4, in order the better to retain the cap 10 in place and to ensure dirt-proof engagement between the tubular walls 11 of the cap 10 and the outer surface of the main body-portion of the second hub-component 5, the distal end of the latter, adjacent the plug portion 7, is provided with an annular groove 12, within which there is accommodated a bulbous sealing ring 13 formed around the skirt-edges of the tubular walls 11 of the cap 10.

In use, a skin-penetration needle 14 (see Figures 2 and 3) is passed through the cap 10, funnelled by the conical indent 9 into the through-passage 3 and, after piercing the self-sealing diaphragm 8, enters and passes through the lumen 16 of the cannula 1, until it extends somewhat beyond the tapered distal end 1' thereof. With the skin-penetration needle thus located, the cannula 1 of the device is then subcutaneously implanted in the patient, the hub-assembly 2 is taped or otherwise secured in place upon the patient (e.g. his abdomen) and the skin-penetration needle is withdrawn, leaving the device indwelling in the patient. There it may remain for several days ready for intermittent or continuous use, as required, for the administration (especially the self-administration) of insulin, morphine or any other therapeutic substance.

Whenever it is appropriate to administer such a therapeutic substance, the needle of the hypodermic injection syringed containing the substance is, as shown in Figure 4, passed in a similar manner through the cap 10. Again the needle is funnelled by conical indent 9 into the through-passage 3, and then pierces the self-sealing diaphragm 8, but this time is there arrested when the syringe-body 15 abuts against the cap 10. Thus, the hypodermic injection syringe is placed in an ideal location adjacent the end of the cannula 1 for the discharge of therapeutic substance from the syringe to the patient through the device.

Referring to Figures 5, 5(a) and 6, the combination there shown comprises a device 21 in accordance with the invention, for example, as described above, and a supply line arrangement generally designated by the numeral 22. The supply line arrangement includes a supply line 23 e.g. a fine bore line, through which a therapeutic substance such as insulin or morphine may be fed e.g. by a pump arrangement, and an end portion 24. The end portion 24 includes a needle 25 e.g. corresponding to the needle of the syringe shown in Figure 4, and a pair of trunnion pins 26 (only one shown).

Mounted on the end portion 24 via the trunnion pins 26 is a locking clip generally designated by the numeral 27. The locking clip 27 comprises a body portion 28 having a first pair of opposed depending arms 29 engageable with the trunnion pins 26 via through apertures 31 whereby the clip 27 can be pivotably mounted on the end portion 24 as shown. The body portion 28 also has a nose portion 32 and a second pair of opposed depending arms 33 which are engageable with annular groove 12 (see also Figure 4) when the needle 25 is passed into the device 21 so that a configuration of needle and device the same as or similar to that shown in Figure 4 is achieved.

Thus, the supply line arrangement 22 and the device 21 may be locked together as shown in Figure 6 so that the patient may receive a therapeutic substance through the line 23. Thereafter, when treatment is complete the combination may be unlocked by inserting a finger under nose portion 32 and lifting the arms 33 out of engagement with the annular groove 12, thus releasing the device 21 from the supply line arrangement 22.

In the accompanying drawings to which the above description relates the relative sizes of certain parts of the device are altered or exaggerated for the purpose of clarity. However, it is to be understood that in practice say the cannula end 1', the lumen 16 and the passage 3 will be closely matched to the needle 14 e.g. as shown for the needle 14 and passage 3 in Figure 2.

As will be appreciated from the above description, the invention provides a device in which accurate placement of the injection or like needle can be accomplished both in terms of alignment and in terms of penetration. In particular, accurate placement in terms of alignment is achieved by providing in accordance with the preferred embodiments described above a hub defining a through-passage so constructed and arranged that the needle is constrained by the diameter of at least part of the through-passage and its alignment with the cannula lumen so that it must enter the lumen as it passes through the self-sealing diaphragm or other separator means rather than penetrate the cannula wall or otherwise be misaligned. Thus, the respective cannula and hub through-passages being at least essentially the same in diameter and at least essentially axially aligned lead to the desired accurate placement.

While the invention is illustrated above by way of example with reference to specific embodiments it is to be understood that the invention is not limited to what is described. Thus, for example, the body of clip 27 may be longer and arms 33 may engage the device 21 nearer its distal end e.g. in another annular groove formed therein beyond groove 12. In that manner the cap 10 may be left in situ in the combination of Figures 5 to 6. Furthermore, as will be appreciated, other arrangements may be employed and numerous variations may be made within the spirit of the invention defined by

the scope of the claims which follow.

Claims

1. A device suitable for use in the intermittent or even continuous administration of a therapeutic substance (such as insulin), which device comprises a cannula (1) of biocompatible plastics material for indwelling in a patient and defining a through-passage (3), together with a hub (2) also defining a through-passage (3), a seal being disposed therebetween the respective cannula (1) and hub (2) passages (3), the arrangement of the respective passages (3) themselves and together with said seal being such as to permit a needle (14) to penetrate the hub (2) and cannula (1), through them and, when of sufficient length, to extend beyond the distal end (1') of the cannula (1), the through-passage (3) of the hub (2) also being so constructed and arranged as to guide an injection needle passed therethrough so that the needle thus guided will pass through the seal at a position where the needle is aligned with the through-passage (3) of the cannula (1), which device is characterised in that said seal comprises a self-sealing diaphragm (8) isolating the respective cannula and hub passages (3), which self-sealing diaphragm (8) is one of a natural rubber, a silicone rubber or another self-sealing elastomeric polymer.

2. A device according to claim 1, wherein the space in the device within which insulin will be withheld instead of being expressed to the patient is about 0.75 units of U-100 insulin or below, preferably from about 0.5 to about 0.3 units of U-100 insulin.

3. A device according to any one of the preceding claims, wherein the mouth of the through-passage (3) in the hub (2) most remote from the cannula (1) is shaped such that the passage has a conical or funnelled entrance zone (9,9').

4. A device according to any one of the preceding claims which includes a penetrable cap (10) to prevent ingress of dirt or other undesirable material when an injection needle is not inserted therein.

5. A device according to any one of the preceding claims, wherein the cannula (1) comprises a flexible synthetic plastics material and preferably comprises medical-implant grade synthetic polymer.

6. A device according to any one of the preceding claims, wherein the hub (2) is a two-part hub-assembly, with the diaphragm (8) located between the two parts of the hub (2).

7. A device according to claim 6, wherein a first hub-component (4) comprises a body defining an axial bore (3) which at its distal end is adapted to receive the proximal end of the cannula (1) whereby the through-passage of the cannula is positioned in communication with the bore, and at its other end a socket (6) communicating with the bore and adapted to receive a plug-portion of a second hub-component (5) also comprising a body defining an axial bore (3), the bores (3) in the respective first and second hub-components being aligned to communicate with each other and together defining the through-passage (3) in the hub-assembly, the self-sealing diaphragm (8) preferably being sandwiched between the two hub-components (4,5).

8. A device according to claim 6 or claim 7, wherein the first hub-component body (4) includes an elongated nose portion at it distal end within which a portion of the proximal end of the cannula (1) can be accommodated, and the bore (3) in the first hub component (4) is preferably of greater diameter than the diameter of the through-passage where it accommodates the tip of the proximal end of the cannula (1), thus providing an annular abutment for the tip of the proximal end of the cannula (1) to permit securing of the cannula (1) to the hub (2).

9. A device according to any one of the preceding claims, which includes a hub (2) having means to provide or accommodate a supply line lock fitment, preferably a hub (2) formed with one or more Luer lock lugs or with means to accommodate a Luer lock adaptor.

10. A device according to claim 7 or claim 8 or claim 9 when dependent thereon, wherein the hub (2) is a two-part hub-assembly, and the hub-components (4,5) are arranged so that the plug-portion of the second hub-component includes an annular flange (17), and the plug-portion mates with the socket (6) in the first hub-component (4) in such a manner that an annular locking groove (12) is formed between the flange (17) and the end of the first hub-component adjacent the flange.

11. A device according to any one of the preceding claims in combination with a skin puncture

needle (14).

12. A device according to any one of claims 1 to 11 in combination with a supply line arrangement (22), preferably a supply line arrangement (22) which includes mounted on an end portion of the line a needle (25) adapted to penetrate the diaphragm of the device and a pivotal clip (27) engageable with the hub (2) of the device (21) to lock together the device (21) and the supply line (22).

Revendications

1. Instrument qui convient à l'emploi pour l'administration intermittente, ou même continue, d'une substance thérapeutique (telle que l'insuline), lequel instrument comprend une canule (1) en une matière plastique biocompatible, destinée à l'introduction dans un patient et délimitant un passage traversant ou trou de passage (3), ainsi qu'une pièce intermédiaire (2) définissant aussi un passage traversant ou trou de passage (3), un joint étanche étant mis en place entre les passages (3) respectifs de la canule (1) et de la pièce intermédiaire (2), l'agencement des passages respectifs (3) eux-mêmes en même temps que du joint étanche précité étant tel qu'il permette à une aiguille (14) de pénétrer dans la pièce intermédiaire (2) et la canule (1) de manière à les traverser et, lorsque de longueur suffisante, à s'étendre au-delà de l'extrémité distale (1') de la canule (1), le passage traversant (3) de la pièce intermédiaire (2) étant également réalisé et agencé de manière à guider une aiguille d'injection qui l'a traversé de façon à ce que l'aiguille ainsi guidée passe à travers le joint étanche en une position où l'aiguille est alignée avec le passage traversant (3) de la canule (1), caractérisé en ce que le joint étanche précité est constitué par un diaphragme (8) autoétanchant, isolant les passages (3) respectifs de la canule et de la pièce intermédiaire, lequel diaphragme autoétanchant (8) est constitué de caoutchouc naturel, de caoutchouc siliconé ou de tout autre polymère élastomérique autoétanchant.

2. Instrument suivant la revendication 1, caractérisé en ce que l'espace de l'instrument dans lequel l'insuline sera retenue au lieu d'être exprimée vers le patient représente environ 0,75 unité d'insuline U-100 ou moins encore, de préférence d'environ 0,5 à environ 0,3 unité d'insuline U-100.

3. Instrument suivant l'une quelconque des revendications précédentes, caractérisé en ce que la bouche du passage traversant (3) dans la pièce intermédiaire (2) la plus éloignée de la canule (1) est façonnée de façon à ce que le passage comporte une zone d'entrée conique ou en forme d'entonnoir (9, 9').

4. Instrument suivant l'une quelconque des revendications précédentes, caractérisé en ce qu'il comprend une coiffe (10) pénétrable, destinée à empêcher l'entrée de crasses ou de tout autre matière indésirable lorsqu'une aiguille d'injection n'y est pas insérée.

5. Instrument suivant l'une quelconque des revendications précédentes, caractérisé en ce que la canule (1) est constituée d'une matière plastique synthétique souple et est, de préférence, constituée d'un polymère synthétique de qualité pour implantation médicale.

6. Instrument suivant l'une quelconque des revendications précédentes, caractérisé en ce que la pièce intermédiaire (2) est constituée par un ensemble en deux parties, le diaphragme (8) étant logé entre les deux parties de la pièce intermédiaire (2).

7. Instrument suivant la revendication 6, caractérisé en ce qu'un premier composant (4) de la pièce intermédiaire comprend un corps délimitant un trou ou passage foré axial (3) qui, à son extrémité distale, est adapté à recevoir l'extrémité proximale de la canule (1) si bien que le passage traversant de la canule est situé de manière à être en communication avec le trou ou passage foré et, à son autre extrémité, est prévue une douille (6) communicant avec le trou ou passage foré et adapté à recevoir une partie-bouchon du second composant (5) de la pièce intermédiaire comprenant également un corps délimitant un passage ou trou foré axial (3) les passages ou trous forés (3) dans les premier et second composants de la pièce intermédiaire étant alignés de manière à mutuellement communiquer et à délimiter ensemble le passage traversant (3) dans l'ensemble constituant la pièce intermédiaire, le diaphragme (8) autoétanchant étant, de préférence, pris en sandwich entre les deux composants (4, 5) de la pièce intermédiaire.

8. Instrument suivant la revendication 6 ou la revendication 7, caractérisé en ce que le corps (4) du premier composant de la pièce intermédiaire comprend une partie allongée formant nez à son extrémité distale dans laquelle peut s'adapter une partie de l'extrémité proximale de la canule (1) et le passage ou trou foré (3)

dans le premier composant (4) de la pièce intermédiaire est, de préférence, d'un diamètre supérieur au diamètre du passage traversant où il s'adapte à la pointe de l'extrémité proximale de la canule (1), constituant ainsi une butée annulaire à la pointe de l'extrémité proximale de la canule (1), de manière à permettre l'assujetissement de la canule (1) à la pièce intermédiaire (2).

9. Instrument suivant l'une quelconque des revendications précédentes, caractérisé en ce qu'il comprend une pièce intermédiaire (2) possédant des moyens qui assurent un ou qui s'adaptent à un raccordement verrouillé à une conduite d'alimentation, de préférence une pièce intermédiaire (2) formé avec une ou plusieurs pièces de verrouillage rôdées ou avec des moyens pour se raccorder à un adaptateur de verrouillage rôdé.

10. Instrument suivant la revendication 7, ou la revendication 8, ou la revendication 9 lorsqu'il en dépend, caractérisé en ce que la pièce intermédiaire (2) est un ensemble en deux parties et les composants (4, 5) de la pièce intermédiaire sont agencés de façon à ce que la partie-bouchon du second composant de la pièce intermédiaire comprend un rebord annulaire 17 et la partie formant bouchon s'apparie à la douille (6) dans le premier composant (4) de la pièce intermédiaire, en une manière telle qu'une rainure ou gorge de verrouillage annulaire (12) soit formée entre le rebord (17) et l'extrémité du premier composant de la pièce intermédiaire, voisine du rebord.

11. Dispositif suivant l'une quelconque des revendications précédentes, en combinaison avec une aiguille hypodermique (14).

12. Dispositif suivant l'une quelconque des revendications 1 à 11, en combinaison avec un agencement de conduite d'alimentation (22), de préférence un agencement (22) qui comprend, montée sur une partie formant l'extrémité de la conduite, une aiguille (25) adaptée à pénétrer dans le diaphragme de l'instrument et un dispositif de retenue ou attache (27) susceptible de pivoter, pouvant coopérer avec la pièce intermédiaire (2) de l'instrument (21) pour verrouiller mutuellement l'instrument (21) et la conduite d'alimentation (22).

Patentansprüche

1. Vorrichtung zur Verwendung bei der zeitweiligen oder sogar kontinuierlichen Verabreichung einer therapeutischen Substanz (wie zum Beispiel Insulin) mit einer Kanüle (1) aus körperverträglichem Kunststoffmaterial, die zum Einbringen in den Körper des Patienten und zur Bildung eines Durchgangs (3) dient und die zusammen mit einer Nabe (2) einen Durchgang (3) bildet, einer Dichtung, die sich zwischen den jeweiligen Kanülen- (1) und Naben- (2) Durchgängen (3) befindet, wobei die Anordnung der jeweiligen Durchgänge (3) selbst und zusammen mit der Dichtung so gestaltet ist, daß eine Nadel (14) durch die Nabe (2) und die Kanüle (1) hindurchdringen und - wenn sie lang genug ist - sich über das distale Ende (1') der Kanüle (1) erstrecken kann, wobei der Durchgang (3) der Nabe (2) ebenfalls so konstruiert und angeordnet ist, um eine Injektionsnadel hindurchzuführen, so daß die so geführte Nadel an einer Stelle durch die Dichtung tritt, an der sie auf den Durchgang (3) der Kanüle (1) ausgerichtet ist, **dadurch gekennzeichnet,** daß die Dichtung eine selbstdichtende Membran (8) aufweist, die jeweils die Kanülen und die Naben-Durchgänge (3) isoliert, wobei die selbstdichtende Membran (8) aus Naturkautschuk, aus Silikonkautschuk oder einem anderen selbstdichtenden elastomeren Polymer besteht.

2. Vorrichtung nach Anspruch 1, wobei der Raum in der Vorrichtung, in dem Insulin zurückgehalten wird, anstatt in den Körper des Patienten hineingeleitet zu werden, ungefähr 0.75 Einheiten von U-100 Insulin oder darunter, vorzugsweise zwischen ungefähr 0.5 bis 0.3 Einheiten von U-100 Insulin aufweist.

3. Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die Öffnung des Durchgangs (3) in der Nabe (2), die von der Kanüle (1) abgewandt liegt, so geformt ist, daß der Durchgang einen kegel- oder trichterförmigen Eingangsbereich (9, 9') hat.

4. Vorrichtung nach einem der vorhergehenden Ansprüche mit einer durchdringbaren Abdekkung (10), um den Eintritt von Schmutz oder anderem unerwünschten Material zu verhindern, wenn keine Injektionsnadel eingeführt ist.

5. Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die Kanüle (1) ein elastisches synthetisches Kunststoffmaterial und vorzugsweise ein synthetisches Polymer von medizinischer Implantatgüte aufweist.

6. Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die Nabe (2) aus einer zwei-

teiligen Nabenanordnung besteht und wobei die Membran (8) zwischen den beiden Teilen der Nabe (2) liegt.

7. Vorrichtung nach Anspruch 6, wobei eine erste Nabenkomponente (4) einen Körper aufweist, in dem eine axiale Bohrung (3) gebildet ist, welche an ihrem distalen Ende das proximale Ende der Kanüle (1) aufnehmen kann, wodurch der Durchgang der Kanüle in Verbindung mit dem Bohrloch liegt, und welche an ihrem anderen Ende eine Fassung (6) hat, die mit der Bohrung in Verbindung steht und einen Stekkerbereich einer zweiten Nabenkomponente (5) aufnehmen kann, die ebenfalls einen Körper aufweist, der eine axiale Bohrung (3) bildet, wobei die Bohrungen (3) in den jeweiligen ersten und zweiten Nabenkomponenten so ausgerichtet sind, daß sie miteinander in Verbindung stehen und zusammen den Durchgang (3) in der Nabenanordnung bilden, wobei die selbstdichtende Membran (8) vorzugsweise zwischen den zwei Nabenkomponenten (4, 5) liegt.

8. Vorrichtung nach Anspruch 6 oder 7, wobei der erste Nabenkomponenten-Körper (4) einen langgestreckten Mündungsbereich an seinem distalen Ende hat, innerhalb dessen ein Teil des proximalen Endes der Kanüle (1) untergebracht werden kann, und wobei die Bohrung (3) in der ersten Nabenkomponente (4) vorzugsweise dort einen größeren Durchmesser hat als der Durchgang, wo sich die Spitze des proximalen Endes der Kanüle (1) befindet, wodurch eine ringförmige Einfassung für die Spitze des proximalen Endes der Kanüle (1) bereitgestellt wird, um die Befestigung der Kanüle (1) an der Nabe (2) zu ermöglichen.

9. Vorrichtung nach einem der vorhergehenden Ansprüche mit einer Nabe (2) mit Mitteln zur Bereitstellung oder Aufnahme eines Zuleitungs-Anschlußeinrichtung, vorzugsweise einer Nabe (2), die mit einem oder mehreren Luer-Verschlußvorsprüngen oder Mitteln zur Aufnahme eines Luer-Verschluß-Adapters gebildet ist.

10. Vorrichtung nach Anspruch 7 oder 8 oder Anspruch 9, falls davon abhängig, wobei die Nabe (2) eine zweiteilige Nabenanordnung ist und die Nabenkomponenten (4, 5) so gestaltet sind, daß der Steckerbereich der zweiten Nabenkomponente einen ringförmigen Flansch (17) aufweist und der Steckerbereich in die Fassung (6) in der ersten Nabenkomponente (4) so eingreift, daß eine ringförmige Verschlußnut (12) zwischen dem Flansch (17) und dem Ende der ersten Nabenkomponente nahe des Flansches gebildet wird.

11. Vorrichtung nach einem der vorhergehenden Ansprüche in Kombination mit einer Injektionsnadel (14).

12. Vorrichtung nach einem der Ansprüche 1 bis 11 in Kombination mit einer Zuleitungsanordnung (22), vorzugsweise einer Zuleitungsanordnung (22), die eine am Ende der Leitung angebrachte Nadel (25) enthält, die die Membran der Vorrichtung durchdringen kann, und einer schwenkbaren Klemme (27), die in Eingriff mit der Nabe (2) der Vorrichtung (21) gebracht werden kann, um die Vorrichtung (21) und die Zuleitung (22) aneinander anzuschließen.

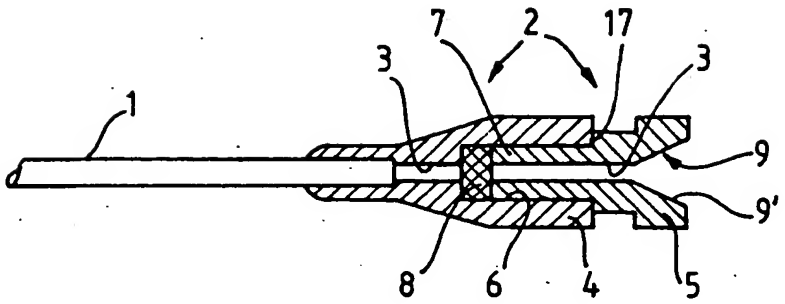

Fig 1

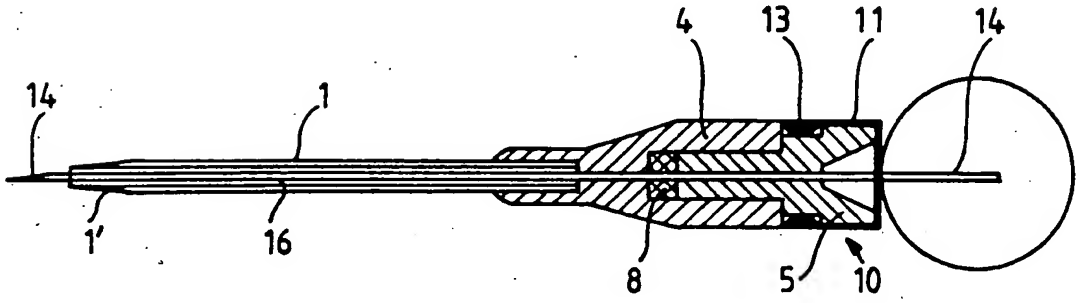

Fig 2

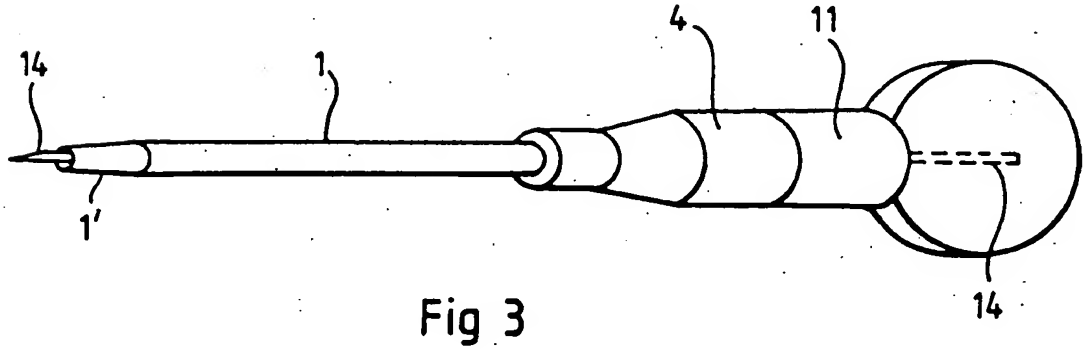

Fig 3

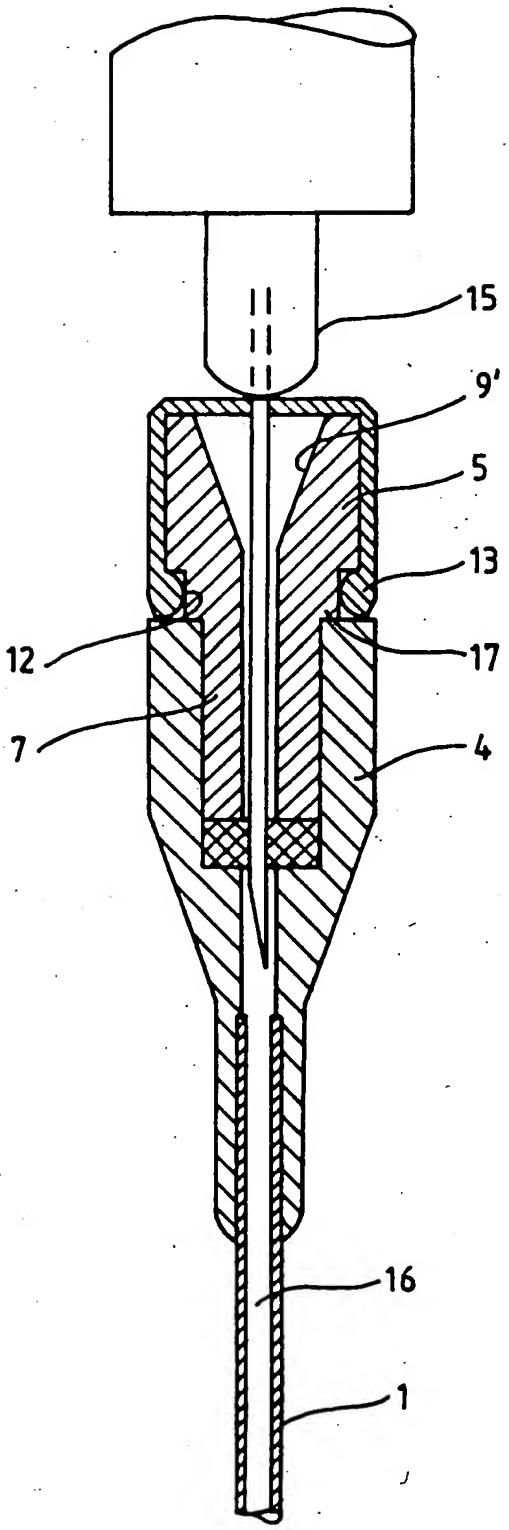

Fig 4

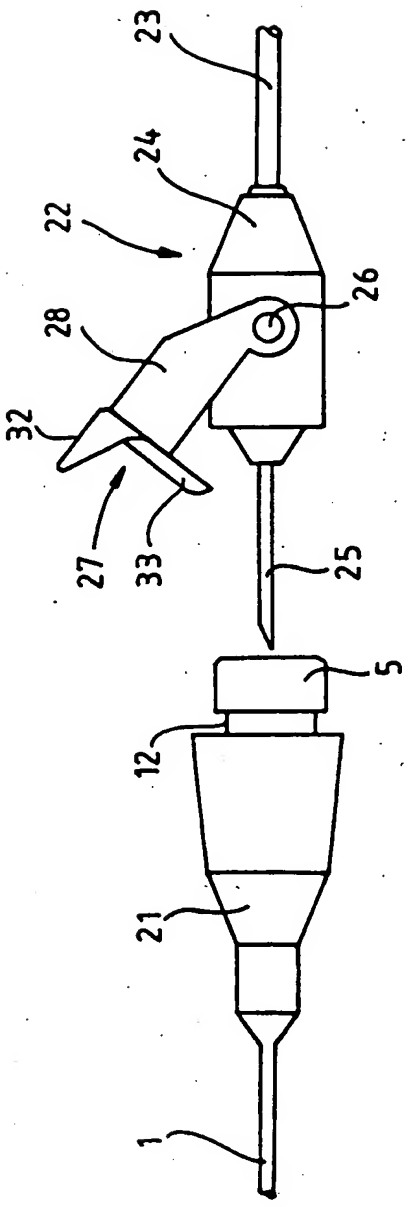

Fig 5

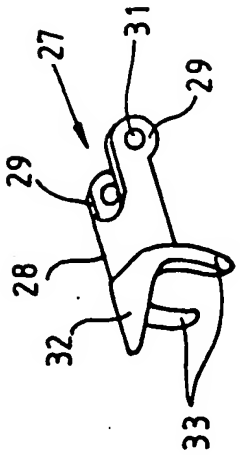

Fig 5a

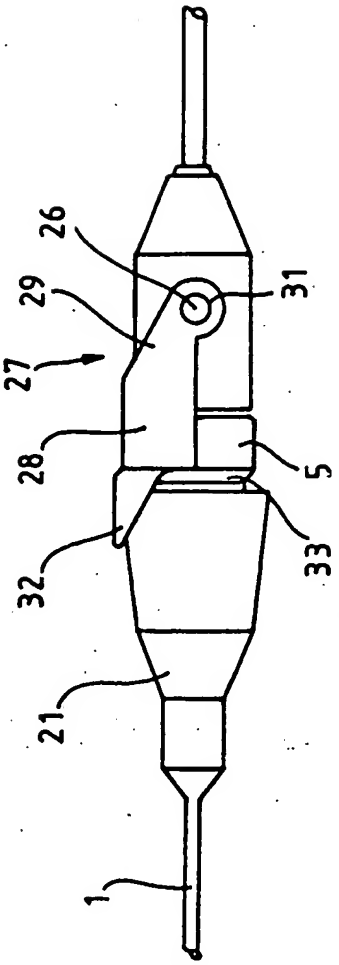

Fig 6